DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 9 2011

Re: CYSVIEW
Patent Nos. 7,247,655 and 7,348,361
Docket Nos. FDA-2011-E-0136
FDA-2011-E-0133

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 7,247,655 and 7,348,361 filed by Photocure ASA, under 35 U.S.C. section 156. The human drug product claimed by the patent is CYSVIEW (hexaminolevulinate hydrochloride), which was assigned new drug application (NDA) No. 22-555.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. section 156(a)(4). FDA confirms that the active ingredient in CYSVIEW, hexaminolevulinate hydrochloride, is an ester of aminolevulinic acid hydrochloride, an active ingredient that has been previously approved for commercial marketing or use as Levulan, NDA 20-965. However, as the term active ingredient is defined under 35 U.S.C. section 156(f)(2) and as recently interpreted by the Federal Circuit,[1] FDA has not previously approved for commercial marketing or use hexaminolevulinate hydrochloride itself, nor a salt or ester of hexaminolevulinate hydrochloride. Consequently, our records indicate that CYSVIEW represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. section 156(a)(5)(A).

The NDA was approved on May 28, 2010, which makes the submission of the patent term extension applications on July 23, 2010, timely within the meaning of 35 U.S.C. section 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

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[1] *See Photocure ASA v. Kappos*, 603 F.3d 1372, 1376 (Fed Cir. 2010).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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